6. 510(k) Summary

APR 2 9 2014

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	CAS Medical Systems, Inc.
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Prepared:	December 16, 2013
Trade Name:	FORE-SIGHT Elite™ Absolute Tissue Oximeter
Common Name:	FORE-SIGHT Oximeter
Classification Name:	Oximeter, Tissue Saturation (870.2700) (MUD)

EQUIVALENCE (Predicate Device)

The FORE-SIGHT Elite™ Absolute Tissue Oximeter is equivalent to the following devices:

- Nonin Model 7600 Regional Oximeter Equanox (K102715)
- FORE-SIGHT Absolute Tissue Oximeter Monitor (K112820)

DESCRIPTION

The FORE-SIGHT Elite Absolute Tissue Oximeter measures hemoglobin under the Sensor, allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO2).

The Oximeter consists of a monitor unit, preamplifier assembly, and sensor. The sensor uses multiple wavelengths in the range of 660 to 900 nm to precisely measure light absorption in tissue. Sensors are sized to provide targeted penetration depths appropriate for the tissue and patient populations of interest. The monitor unit controls the measurement sequence, generating the sensor LED currents and processing the detected light signals after amplification by the dual-channel preamplifier assembly. The FORE-SIGHT algorithm determines the StO2 values for the tissue under the sensor from the light absorption values and measured patient characteristics. The monitor unit provides simultaneous measurements on up to four sensors with both numeric and real-time graphical display formats.

The monitor unit is a mains-powered device with a field-replaceable battery backup module. A touchscreen user interface allows configuration of the Oximeter including audible, on-screen, and dedicated visual alarm indicators. The monitor display can be replicated for simultaneous remote viewing through an auxiliary VGA video output. Measurement data can be exported through various interfaces such as USB, RS-232 serial or wireless communications.

FORE-SIGHT Oximeter Monitor Intended Use

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows:

When used with large sensors, the FORE-SIGHT ELITE Oximeter is indicated for use on adults and transitional adolescents ≥40 kg.

FORE-SIGHT Monitor Technology Compared to Predicate Devices

The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the cited predicate devices in that they use fundamentally the same optical operating principle, called multi-distance diffuse reflectance spectroscopy. All cited monitors use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT Elite Monitor and predicate devices analyze the light that is returned after having passed through tissues. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states. All cited monitors calculate oxygen saturation which reflects the percentage of oxygenated hemoglobin in the sampled tissue.

The FORE-SIGHT Elite Absolute Tissue Oximeter compares substantially to the predicates. All have 4-channel capability, an LED light source, similar user interface features and the benefits of portability.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT Elite Absolute tissue Oximeter has successfully undergone extensive performance, safety, electromagnetic, clinical, software and environmental testing to ensure it has been found to be substantially equivalent to the predicate devices. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software, systems verification and validation studies of the FORE-SIGHT monitor and sensors.

Clinical Testing to Show Substantial Equivalence

The FORE-SIGHT Elite Absolute Tissue Oximeter has successfully undergone extensive clinical validation for the indicated use. The premarket notification cites a validation report: **Validation of the CAS Medical System's FORE-SIGHT Elite™ Absolute Tissue Oximeter for Somatic Tissue Oxygen Saturation (StO2%) in Adult and Transitional Adolescent Subjects.**

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing and software validation demonstrate the FORE-SIGHT Elite Absolute Tissue Oximeter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

Cas Medical Systems, Inc.
Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Rd.
Branford, Connecticut 06405

Re: K133879
Trade/Device Name: Fore-Sight Elite Absolute Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Tissue Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: March 28, 2014
Received: March 31, 2014

Dear Ron Jeffrey,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K133879

Indications for Use

510(k) Number:

Device Name: FORE-SIGHT Elite™ Absolute Tissue Oximeter.

Indications for Use:

The noninvasive FORE-SIGHT Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated for use as follows:

When used with large sensors, the FORE-SIGHT Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)